



**Comments of The National Health Council  
on the Food and Drug Administration  
Critical Path Initiative  
(Notice 2004-N-0181)**

Submitted to:  
Food and Drug Administration  
Division of Dockets Management (HFA-305)  
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The National Health Council is pleased to submit these comments in response to the Notice of Comment on the Food and Drug Administration's Critical Path Initiative (2004N-0181), released on April 22, 2004.

The National Health Council, a private, nonprofit umbrella organization of more than 110 national health-related organizations, works to bring quality health care to all people. Its core membership includes more than 50 of the nation's leading voluntary health agencies (patient-based organizations), including the American Cancer Society, American Heart Association, Arthritis Foundation, American Autoimmune Related Diseases Association, The ALS Association, Alpha-1 Foundation and the Epilepsy Foundation—all groups representing approximately 100 million people with chronic diseases and/or disabilities. Other Council membership categories include professional and membership associations such as the American Academy of Family Physicians, nonprofits organizations with an interest in health such as AARP, and business and industry including Pfizer Inc, and Amgen Inc.

The National Health Council is pleased that the Food and Drug Administration (FDA) is seeking to obtain input from all stakeholders pertaining to the development and design of medical products, and looking for ways to improve the pace and effectiveness of this process as well as potentially reducing the costs. Bringing new and effective treatments to patients with chronic diseases and/or disabilities is a key priority for the Council and its members. However, ensuring the safety of such products is of tantamount concern, as is ensuring that any new products that reach the market are affordable and accessible to all patients who need them. We applaud the FDA for incorporating this issue into its thinking and encourage FDA to continue to seek ways to enhance the safety and efficacy of medical products while at the same time lowering the cost of development and production.

First and foremost, the Council considers the safety of patients, from clinical research to post-market consumption of products, as the number one priority. We agree that standardization of data collection and submission is a crucial tool to help the FDA review, evaluate, and analyze clinical trial data, and will help lead to greater efficiencies in clinical research and FDA review of New Drug Applications (NDAs). There should also be a new focus on developing better predictive models, using new computer technologies whenever possible, for testing the safety of compounds in the early stages of clinical research.

Many patients have multiple chronic conditions that may require multiple medications, supplements, and other dietary restrictions. We commend FDA for recognizing the shift to a chronic care paradigm in health care, and recommend that FDA work closely with academic and industry scientists to develop clinical trials and predictive models that will address the issues of co-morbidities and polypharmacy.

The Council also encourages FDA to work with other federal research agencies and the private/academic sectors to promote the development of tools and techniques to better evaluate, analyze, and predict the safety and efficacy of new compounds and medical products. The National Institutes of Health's "Roadmap" initiative, which focuses on bringing together scientists from multiple disciplines to further the knowledge in basic and translational science, serves as a good model for FDA's work on critical path research.

In addition, the Council recommends that FDA should work to ensure that a repository of studies and published data are catalogued and readily available in an easy-to-navigate format. Previous research can provide tremendous value to scientists, potentially leading to new discoveries at reduced costs.

### **Conclusion**

The National Health Council is pleased that FDA is working to provide more innovative products to patients, with lowered costs and enhanced safety and efficacy profiles. We look forward to collaborating with the FDA and other stakeholders to bring scientific advances into the product development process. We thank you for this opportunity to comment on this important initiative.

